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10/694,180	10/28/2003	William Travis Young	34382-60266	2749

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EXAMINER	
CHORBAJI, MONZER R	
ART UNIT	**PAPER NUMBER**
1797	

NOTIFICATION DATE	DELIVERY MODE
12/13/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/694,180	YOUNG ET AL.	
	Examiner	Art Unit	
	MONZER R. CHORBAJI	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This non-final action is in response to the RCE/Amendment received on 05/04/2007

Claim Objections

1. Claims 1 and 14 are objected to because of the following informalities: In line 8 claim 1, the unit "mg/l" should be replaced with "mg/L". In line 13 of claim 14, Applicant added a temperature range for the heated nitrogen without including the Fahrenheit unit as described on page 1, numbered line 23 of the disclosure. Also in line 13, the word "stream" should be replaced with "steam". Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-2, 5-6, 10-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

For claim 1: lines 6-7, Applicant has added the limitation "mercury to value of first evacuating step" whereas the specification on page 3, numbered lines 29-31, recites "near the value of the initial evacuation". In line 8, Applicant added the sterilant concentration range of "150 to 550 mg/L" whereas the specification on page 4,

numbered line 19, teaches a range of "400 to 550 mg/L". In lines 14-15, the specification only discloses one step of overpressure in the range of 5-15 inches of mercury. However, lines 10-11 of claim 1, state one step and lines 14-15 of claim 1 recite a second overpressure step. The specification does not disclose two steps. In line 16, the specification only discloses degassing the product with an inert gas, not using steam. Also, the specification does not teach the step degassing the product by "a gas wash". The specification on page 6 only teaches a "degassing step".

For claim 2, the specification only discloses that ethylene oxide is a sterilant not an inert gas. For example, see page 4.

For claim 5, Applicant has added the limitations "said evacuation of said chamber includes the step of real-time monitoring said concentration of ethylene oxide in the headspace". These added limitations only have support in the specification for during the dwell time, not the evacuation step.

For claims 6 and 10, Applicant has added the limitations of "pressurizing said single chamber with 3 to 50 inches of mercury". The specification on page 6, discloses different ranges of pressure.

For claim 14, lines 3-6, the specification discloses that steam is for raising temperature and introducing humidity and inert gas is only to raise the temperature; however, the claim implies that both can be true in both instances. Also, in lines 16-17, the specification does not teach the step degassing the product by "a gas wash". The specification on page 6 only teaches a "degassing step". Furthermore, the specification only discloses degassing the product with an inert gas, not using steam.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-8 and 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For claim 1, lines 6-7, Applicant has added the limitation "mercury to value of first evacuating step". The wording of this phrase is unclear. It should be –mercury to near a chamber pressure value of said first evacuating step--. In line 12, "for product" should be "for the product", unclear language. In lines 14-15, the specification only discloses one step of overpressure in the range of 5-15 inches of mercury. However, lines 10-11 of claim 1, state one step and lines 14-15 of claim 1 recite a second overpressure step. It is unclear whether this is an additional step or the same step.

For claim 2, it is unclear which inert gas is being referred to, and how can the inert gas be Nitrogen and ethylene oxide.

For claim 4, Applicant has added the limitation "heated insert gas". The wording of this phrase is unclear. It should be --heated inert gas--.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-4, 6 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joslyn (U.S.P.N. 4,770,851) in view of Popescu et al (U.S.P.N. 5,464,580).

Regarding claim 1, Joslyn discloses a method for sterilizing industrial products (col.1, lines 12-14) including, in combination, the steps of conditioning industrial products to be sterilized by placing the products in a single chamber (figure 1:16), first evacuating the single chamber (col.3, lines 37-39) to a certain vacuum pressure, adding heated air into the single chamber (col.3, lines 57-58) to increase chamber pressure

and re-evacuating the single chamber (col.4, lines 1-3) by pulling the heated air from the chamber by a certain vacuum pressure amount to return to the value of the first evacuating (figure 2: points 102 and 106 where both values represent P1), and sterilizing the products by injecting a sterilant gas into the single chamber (col.4, lines 31-32) to raise the chamber pressure by a certain amount (figure 1:111 and col.4, lines 33-34) with ethylene oxide gas having a concentration value of 650 mg/L (see Table 2), where Joslyn uses the ethylene oxide gas as the overpressure gas instead of using an inert gas as required by the claim (col.4, lines 63-65), holding the product in the single chamber for a dwell time (see the two hours ethylene oxide sterilization described in Table 2) determined for product being sterilized until the products is sterilized, at initiation of dwell time, Joslyn adds ethylene oxide (considered as the gas overlay) instead of an inert gas as required by the claim (col.4, lines 31-38) for duration of the dwell time (see Table 1) where the pressurized chamber has a certain pressure value, degassing the product by a gas wash that includes steam (col.5, lines 9-10) and by evacuating the chamber to a certain pressure value (considered P1 in figure 3 and as described in col.5, lines 15-18) and re-pressurized with heated air to a certain pressure value (col.5, lines 29-32) with necessary repetitions of evacuating and re-pressuring the chamber to degas the products (col.6, lines 25-32), releasing the degassed products after the steps of conditioning the products, sterilizing the products, and de-gassing the products are completed (col.6, lines 32-34) to validated process parameters (col.6, lines 37-45 and Table 2) which render to the products specific product and process evidence of appropriate level of lethality and residual reduction. As to the limitation to the

concentration limitation of the sterilant being from150 to 550 mg/L, Joslyn discloses an ethylene oxide gas concentration value of 650 mg/L as an exemplary value (Table 2) without requiring the concentration of ethylene oxide to be only limited to the value shown in Table 2. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to decrease Joslyn's ethylene oxide concentration value from 650 mg/L to 550 mg/L or lower since Joslyn disclosure does not require sterilizing products at only 650 mg/L and does not exclude other sterilant concentration values as well. It is noted in the specification on page 4, numbered lines 18-20, that Applicant does not provide criticality to the concentration of ethylene oxide gas being at 550 mg/L. Joslyn does not specifically describe the following: evacuating to a pressure of from 1 to 4 inches of mercury, adding pulsing steam and heated inert gas into the single chamber to increase chamber pressure by at least 2 inches of mercury, re-evacuating by pulling the inert gas from the chamber by 2 inches of mercury, injecting the sterilant into the single chamber to raise the chamber pressure by at least 9 inches of mercury, introducing an overpressure of inert gas into the single chamber in the range of from 5 to 15 inches of mercury; at initiation of dwell time, adding an inert gas overlay of an inert gas blanket overpressure for duration of the dwell time in the range of from 5 to 15 inches of mercury, degassing the products to a pressure of less than 3 inches of mercury and re-pressurizing with inert gas to a pressure of from less than 3 to up to 55 inches of mercury. Popescu discloses a method for sterilizing industrial products with ethylene oxide gas (col.1, lines 6-11) that includes the following: evacuating to a pressure of from 1.77 inches of mercury (col.5, lines 25-26 where 6 Kpa

equals 2 inches of mercury) in order to remove residual nitrogen present from the end of previous sterilization cycle (col.5, lines 21-23), adding steam (col.5, lines 25-26) and heated inert gas (col.5, lines 38-39) into the sterilization chamber (figure 1:10) in order to humidify the products to be sterilized (col.5, lines 26-27) to increase chamber pressure by at least 2 inches of mercury (col.5, lines 39-40), re-evacuating by pulling the inert gas from the chamber by 2 inches of mercury (col.5, lines 25-26) in order to remove residual ethylene oxide (col.6, lines 12-13), injecting the sterilant into the chamber (figure 1:10) to raise the chamber pressure by at least 9 inches of mercury (col.5, lines 40-42), introducing an overpressure of inert gas into the single chamber in the range of from 5 to 15 inches of mercury (col.5, lines 38-40) at the initiation of dwell time where nitrogen is added as a gas overly of an inert gas blanket overpressure for the duration of the dwell time (col.5, lines 44-45) because the use of pure nitrogen rather than air to repressurizes the vessel significantly reduces the possibility of inadvertently forming an explosive mixture of ethylene oxide and oxygen (col.5, lines 55-58), degassing the products to a pressure of less than 3 inches of mercury (col.6, lines 22-23) in order to eliminate residual ethylene oxide and moisture from the sterilized products (col.6, lines 12-13) and re-pressurizing with inert gas to a pressure of from less than 3 to up to 55 inches of mercury (col.6, lines 21-22), because ethylene oxide is toxic and it needs to be substantially removed from the sterilized products (col.6, lines 15-16). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the method in Joslyn with the nitrogen gas because the use of pure nitrogen rather than air to repressurizes the vessel

significantly reduces the possibility of inadvertently forming an explosive mixture of ethylene oxide and oxygen as shown by Popescu (col.5, lines 55-58) and to further provide the method in Joslyn with the vacuum pressure values in order to remove residual nitrogen present from the end of previous sterilization cycles as described by Popescu (col.5, lines 21-23).

Regarding claim 14, Joslyn discloses a method for sterilizing industrial products (col.1, lines 12-14) including, including, in combination, the steps of conditioning industrial products to be sterilized by placing the products in a single chamber (figure 1:16), evacuating the single chamber (col.3, lines 37-39) to a certain vacuum pressure, adding heated air into the single chamber (col.3, lines 57-58) to raise the temperature of the products (one of ordinary skill in the art would recognize that adding heated air will increase the temperature within the sterilizing chamber,16, of Joslyn), sterilizing the industrial products by injecting ethylene oxide gas into the chamber (col.4, lines 31-32) to raise the chamber pressure by a certain amount of pressure (figure 1:111 and col.4, lines 33-34) with ethylene oxide gas concentration of 650 mg/1 of sterilants gas (see Table 2), which acts as an overpressure gas into the single chamber (col.4, lines 36-38) having a certain pressure value, holding the product in the single chamber for a dwell time (see the two hours ethylene oxide sterilization described in Table 2) while the product is sterilized, evacuating the chamber to a certain pressure value (considered P1 in figure 3 and as described in col.5, lines 15-18), adding steam into the single chamber (col.5, lines 15-19), injecting the single chamber with warm air (col.5, lines 29-30), and degassing the products by a gas wash that includes steam (col.5, lines 9-10) and by

evacuating the chamber to a certain pressure value (considered P1 in figure 3 and as described in col.5, lines 15-18) and re-pressurized with heated air to a certain pressure value (col.5, lines 29-32) with necessary repetitions of evacuating and re-pressuring the chamber to degas the products (col.6, lines 25-32) without specified holding times (col.6, lines 27-32), releasing the degassed products after the steps of conditioning the products, sterilizing the products, and de-gassing the products are completed (col.6, lines 32-34) to specific product parameters (col.6, lines 37-45 and Table 2). Joslyn does not specifically describe introducing 5 to 15 inches of nitrogen overpressure into the chamber and evacuating the single chamber to a pressure of from 1 to 3 inches of mercury. Popescu discloses a method for sterilizing industrial products with ethylene oxide gas (col.1, lines 6-11) that includes evacuating the sterilizing chamber (figure 1:10) to a pressure of from 1.77 inches of mercury (col.5, lines 25-26 where 6 Kpa equals 2 inches of mercury) in order to remove residual nitrogen present from the end of previous sterilization cycle (col.5, lines 21-23) and introducing an overpressure of nitrogen gas into the single chamber in the range of from 5 to 15 inches of mercury (col.5, lines 38-40), because the use of pure nitrogen rather than air to repressurizes the vessel significantly reduces the possibility of inadvertently forming an explosive mixture of ethylene oxide and oxygen (col.5, lines 55-58). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the method in Joslyn with the nitrogen gas because the use of pure nitrogen rather than air to repressurizes the vessel significantly reduces the possibility of inadvertently forming an explosive mixture of ethylene oxide and oxygen as shown by Popescu

(col.5, lines 55-58) and to further provide the method in Joslyn with the vacuum pressure values in order to remove residual nitrogen present from the end of previous sterilization cycles as described by Popescu (col.5, lines 21-23).

Regarding claim 3, Joslyn sterilizes industrial products with ethylene oxide in a single chamber (figure 1:16) by evacuating the single chamber (col.4, lines 1-3 and figure 2:106 and 107) after holding the products in the single chamber and adding steam (col.3, lines 44-47) into the single chamber.

Regarding claims 2 and 4, Joslyn does not specifically describes the use of heated nitrogen gas. Popescu discloses a method for sterilizing industrial products with ethylene oxide gas (col.1, lines 6-11) that includes adding heated nitrogen gas (col.5, lines 38-39) into the sterilization chamber (figure 1:10) because the use of pure nitrogen rather than air to repressurizes the vessel significantly reduces the possibility of inadvertently forming an explosive mixture of ethylene oxide and oxygen (col.5, lines 55-58). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the method in Joslyn with the heated nitrogen gas because the use of pure nitrogen rather than air to repressurizes the vessel significantly reduces the possibility of inadvertently forming an explosive mixture of ethylene oxide and oxygen as shown by Popescu (col.5, lines 55-58).

Regarding claims 6, 13 and 15, Joslyn discloses degassing the products by evacuating the single chamber (col.5, lines 15-16) and then pressurizing it with heated air (col.5, lines 29-30) and repeating until the products are degassed (col.6, lines 25-32). Joslyn does not specifically disclose pressure values for vacuum or for pressurizing

and also does not specifically teach the use of nitrogen. Popescu discloses a method for sterilizing industrial products with ethylene oxide gas (col.1, lines 6-11) that includes the following: evacuating to a pressure of from 1.77 inches of mercury (col.5, lines 25-26 where 6 Kpa equals 2 inches of mercury) in order to remove residual nitrogen present from the end of previous sterilization cycle (col.5, lines 21-23), introducing an overpressure of inert gas into the single chamber in the range of from 5 to 15 inches of mercury (col.5, lines 38-40) at the initiation of dwell time where nitrogen is added as a gas overly of an inert gas blanket overpressure for the duration of the dwell time (col.5, lines 44-45) because the use of pure nitrogen rather than air to repressurizes the vessel significantly reduces the possibility of inadvertently forming an explosive mixture of ethylene oxide and oxygen (col.5, lines 55-58) and the rate of degassing is in the range of 0.1 to 0.5 inches per minute (col.6, lines 27-28, 0.83 Kpa/min is equivalent to 0.24 inches of mercury/min). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the method in Joslyn with the nitrogen gas because the use of pure nitrogen rather than air to repressurizes the vessel significantly reduces the possibility of inadvertently forming an explosive mixture of ethylene oxide and oxygen as shown by Popescu (col.5, lines 55-58) and to further provide the method in Joslyn with the vacuum pressure values in order to remove residual nitrogen present from the end of previous sterilization cycles as described by Popescu (col.5, lines 21-23).

Regarding claim 16, Joslyn uses ethylene oxide to sterilize industrial products by adding steam into the single chamber (figure 1:16) and is repeated one or more times

(col.6, lines 21-32).

10. Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joslyn (U.S.P.N. 4,770,851) in view of Popescu et al (U.S.P.N. 5,464,580) as applied to claim 5 and further in view of Stewart et al (U.S.P.N. 5,882,590).

Regarding claim 5, Joslyn evacuates the single chamber (for example in col.3, lines 37-39) without specifically disclosing vacuum pressure values and also does not specifically teach placing real-time ethylene oxide monitors in the headspace of the chamber. Popescu discloses a method for sterilizing industrial products with ethylene oxide gas (col.1, lines 6-11) that includes evacuating to a pressure of from 1.77 inches of mercury (col.5, lines 25-26 where 6 Kpa equals 2 inches of mercury) in order to remove residual nitrogen present from the end of previous sterilization cycle (col.5, lines 21-23). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the method in Joslyn with the vacuum pressure values in order to remove residual nitrogen present from the end of previous sterilization cycles as described by Popescu (col.5, lines 21-23).

Popescu does not specifically teach placing real-time ethylene oxide monitors in the headspace of the chamber. Stewart uses real-time monitoring method (col.1, lines 6-8) where various parametric sterilization variables (col.3, lines 38-43) are sensed including a real-time ethylene oxide concentration sensor (col.3, lines 43 and 63) by placing this sensor in the headspace of the sterilization chamber (figure 1:1 and 8) in order to assure that critical concentration parameter values have been met (col.2, lines

61-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the method in Joslyn with the concentration real-time sensor being placed in the headspace of the chamber in order to assure that critical concentration parameter values have been met as shown by Stewart (col.2, lines 61-65).

Regarding claim 10, wherein Joslyn teaches evacuating the single chamber (for example, col.3, lines 37-39), pressurizing the single chamber (figure 1:16) with heated air (col.3, lines 57-58) and repeating (col.6, lines 25-32) until the product is degassed. Joslyn does not specifically disclose pressurizing values and also does not specifically teach the use of nitrogen gas. Popescu discloses pressurizing the sterilization chamber (figure 1:10) with 3 to 50 inches of mercury with nitrogen (col.6, lines 21-22), because ethylene oxide is toxic and it needs to be substantially removed from the sterilized products (col.6, lines 15-16). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the method in Joslyn with the nitrogen gas because ethylene oxide is toxic and it needs to be substantially removed from the sterilized products as explained by Popescu (col.6, lines 15-16).

11. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joslyn (U.S.P.N. 4,770,851) in view of Popescu et al (U.S.P.N. 5,464,580), Stewart et al (U.S.P.N. 5,882,590) as applied to claim 5 and further in view of Kolstad et al (U.S.P.N. 4,973,449).

Regarding claim 11, Joslyn, Popescu and Stewart do not specifically teach evacuating the single chamber down to 3 to 7 inches of mercury and pulsing the

chamber with 5 to 9 inches of heated nitrogen gas. Kolstad teaches pulsing by evacuating the chamber down to 3 to 7 inches of mercury and pulsing the chamber with 5 to 9 inches of heated nitrogen gas (col.5, lines 30-36) in order to subject the contents of the sterilization chamber to pressure differential pulses of significant magnitude in the presence of the biocidal chemical vapors for more efficient sterilization of the contents (col.5, lines 30-41). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Joslyn method by including the pulsing process of Kolstad in order to subject the contents of the sterilization chamber to pressure differential pulses of significant magnitude in the presence of the biocidal chemical vapors for more efficient sterilization of the contents as described by Kolstad (col.5, lines 30-41).

Regarding claim 12, Joslyn degassing step is further accomplished by injecting the single chamber (figure 1:16) with warm air (col.5, lines 29-30).

12. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joslyn (U.S.P.N. 4,770,851) in view of Popescu et al (U.S.P.N. 5,464,580) as applied to claim 3 and further in view of Kolstad et al (U.S.P.N. 4,973,449).

Regarding claim 7, Joslyn and Popescu do not specifically teach evacuating the single chamber down to 3 to 7 inches of mercury and pulsing the single chamber with 5 to 9 inches of heated nitrogen gas. Kolstad teaches pulsing by evacuating the chamber down to 3 to 7 inches of mercury and pulsing the chamber with 5 to 9 inches of heated nitrogen gas (col.5, lines 30-36) in order to subject the contents of the sterilization chamber to pressure differential pulses of significant magnitude in the presence of the

biocidal chemical vapors for more efficient sterilization of the contents (col.5, lines 30-41). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Joslyn method by including the pulsing process of Kolstad in order to subject the contents of the sterilization chamber to pressure differential pulses of significant magnitude in the presence of the biocidal chemical vapors for more efficient sterilization of the contents as described by Kolstad (col.5, lines 30-41).

Regarding claim 8, Joslyn describes that the step of degassing is further accomplished by injecting the single chamber with warm air (col.5, lines 29-30).

Response to Arguments

13. Applicant's arguments with respect to claims 1-8 and 10-16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sell et al (U.S.P.N. 5,069,061) describes the use of headspace analysis in a sealed enclosure in combination with the use of ethylene oxide gas.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 9:00-5:30.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GLADYS J. CORCORAN can be reached on (571) 272-1214.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MRC

GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER